MAY 31 2001

SECTION E **510(k) SUMMARY**

510(k) Number: K002847

Trade Name: Introducer with Distal Radiopaque Marker Band

Common Name: Catheter Introducer

Classification Name: Catheter Introducer (per CFR 21 Part 870.1340, 74 DYB)

Product Code: DYB

Classification: Class II

Submitted by: Maxxim Medical, Athens Facility
1445 Flat Creek Road
Athens, TX 75751
Phone: 903-675-9321
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Contact person: Gail Doherty, QA/RA

Date prepared: 9/11/00

Legally marketed devices to which equivalence is claimed:

Maxxim Medical Introducer for PTCA Guiding Catheters, K891022

Description of Device:

The 'Introducer with Distal Radiopaque Marker' can be used with a needle, guidewire and vessel dilator and utilized in procedures for percutaneous introduction of intravascular devices. The introducer features a sheath constructed from a fluoropolymer (FEP) mechanically bonded to a hemostasis valve, that has proximal screw-type connector, for dilator attachment. The introducer incorporates a radiopaque band within the sheath for enhanced radiopacity. There is a side-port with stopcock to allow fluids to enter below the hemostasis valve. On some lengths, the distal tip is curved to provide easier access to the vasculature.

Scientific concepts that form the basis for the device:

The 'Introducer with Distal Radiopaque Marker Band' features a sheath constructed from FEP for enhanced lubricity and to help maintain the curve during procedural use. A radiopaque band, incorporated within the sheath, identifies the precise location of the distal tip for positioning. The hemostasis valve minimizes blood reflux and air aspiration. The side-port and stopcock allow flushing around the catheter while it is positioned within the sheath and can be used as a second infusion line. The distal tip is curved to provide easier access to the some parts of the vasculature.

Intended Use of Device:

The Maxxim Medical Introducers are indicated for use in arterial and venous procedures requiring percutaneous introduction of intravascular devices. Curved tip introducer allows for contralateral access to the iliac artery and selected vasculature. Radiopaque banded introducers identify location of Introducer distal tip for positioning.

Comparison of Technological Characteristics to legally marketed device:

The 'Introducer with Distal Radiopaque Marker Band' is being compared to the Maxxim Medical Introducer for PTCA Guiding Catheters.

The predicate device has a FEP sheath for passage of devices, a proximal hemostasis valve and a side-port with stopcock, as does the 'Introducer with Distal Radiopaque Marker Band'. However, the predicate device has a luer fitting connector and the 'Introducer with Distal Radiopaque Marker Band' has a similar screw-type connector, but of reduced height. A radiopaque band is incorporated within the sheath of the 'Introducer with Radiopaque Band' for enhanced fluoroscopic visualization of the tip, while the predicate device does not possess this. Some models of the 'Introducer with Distal Radiopaque Marker Band' possess a curved distal tip to provide better access to certain vasculature, which the predicate device does not contain. The differences stated do not affect the safety and effectiveness of the device. The 'Introducer with Distal Radiopaque Marker Band' has been completely tested for biocompatibility according to the FDA's General Program Memorandum #G95-1, and International Standard ISO-10993, "Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing", May 1, 1995.

Performance Data:

The comparative testing follows the essence of the testing detailed in the regulatory guidance document, ISO Standard 11070, Sterile single-use intravascular catheter introducers (5-1-98). The following tests demonstrated substantial equivalence:

1) Radiopacity
2) Tensile Strength of Distal Curve
3) Scratch Test for Heat Shrink TFE
4) Air Leakage from Fitting Assembly Under Positive and Negative Pressure
5) Liquid Leakage from Fitting Assembly Under Pressure
6) Hub according to ISO 594-2
   6.1) Separation Force of Fitting Assembly
   6.2) Unscrewing Torque of Fitting Assembly
   6.3) Resistance to Overriding
   6.4) Ease of Assembly

Test results demonstrate that the Introducer with Distal Radiopaque Marker Band is substantially equivalent to the Maxxim Medical Introducer for PTCA Guiding Catheters.

Packaging and Sterilization Information

The predicate device, Introducer for PTCA Guiding Catheters introducer has a shelf-life of 5 years. Accelerated testing of the distal banded introducer has also demonstrated a 5-year shelf-life and thus this product shall also be marketed with a 5 year shelf-life from the date of packaging. The device is sold sterile, for single use only. It may be sold as a single-put-up with a dilator or part of a "kit" that includes the other components required to perform the desired procedure.

Sterilization for Maxxim Medical is by a validated ethylene oxide sterilization (EtO) method that is referenced in ANSI/AAMI/ISO 11135-1994 "MEDICAL DEVICES-Revalidation and Routine Control of Ethylene Oxide Sterilization."

CONCLUSIONS:

Maxxim Medical concludes that the 'Introducer with Distal Radiopaque Marker' is substantially equivalent to the Introducer for PTCA Guiding Catheters:

1) functionally and
2) with regards to safety and effectiveness

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 31 2001

Ms. Gail Doherty
Manager, Quality Assurance
MAXXIM Medical
1445 Flat Creek Road
P.O. Box 1970
Athens, TX 75751

Re: K002847
Inroducer with Distal Radiopaque Marker Band, Model
Regulation Number: 870.1340
Regulatory Class: II (two)
Product Code: 74 DYB
Dated: March 9, 2001
Received: March 13, 2001

Dear Ms. Doherty:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002847

Device Name: Introducer with Distal Radiopaque Marker Band

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K002847

(Optional Format 3-10-98)